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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,032	02/05/2004	Frank D. Lee	EPTM-P03-001	5991
28120	7590	12/28/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,032

Applicant(s)

LEE ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6 pages.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-36 in the reply filed on October 5, 2005 is acknowledged. The traversal is on the ground(s) that a search for Group I will include a search for Group II. Upon reconsideration of the claims, the claims of Group I and Group II have been rejoined.

Petition to Make Special

The grant of the petition to make special, filed August 3, 2005, is acknowledged. However, Applicants must elect without traverse in response to a restriction requirement in order to maintain the special status of their application. (See MPEP §708.02) Applicants elected with traverse on October 6, 2005. The special status of the instant application is hereby withdrawn.

Claim Objections

Claim 1 is objected to because of the following informalities: using the word "which" in line 4 of the instant claim is grammatically wrong. Appropriate correction is required.

Claim 4 is objected to because of the following informalities: the word "agent" is misspelled. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: the word "categories" is misspelled. Appropriate correction is required.

Claim 29 is objected to because of the following informalities: the word "small" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the results" in line 12. There is insufficient antecedent basis for this limitation in the claim. In step 3, there is no mention of "the results."

Claim 1 recites the term "selectively interacts" in line 5. It unclear if "selectively" means that the capture agents will only bind to a peptide tag of a target protein, or if the capture agents will bind to a few different peptide tags.

Claim 1 recites the limitation "the interaction" in line 10. There is insufficient antecedent basis for this limitation in the claim. There has been no mention of interaction in the previous steps.

Claim 3 recites the limitation "the same category". There is insufficient antecedent basis for this limitation in the claim. This limitation was not mentioned previous in the claim of in the claims from which it depends.

Claims 32-36 recite the limitation "The array". There is insufficient antecedent basis for this limitation in the claims. There is no mention of an array in instant claim 29, from which these instant claim depends.

Regarding claim 20, the parenthetical statement "(zebra fish)" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 33 and 35 recites the limitation "said array device". There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "said beads". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ault-Riche et al. (US 2003/0143612 A1) in view of Wagner et al. (US 6,897,073 B2).

Regarding claims 1, 14, 15, 30, 31 and 37, Ault-Riche et al. teach providing two or more capture agents for detecting a target protein in a test sample in an addressable array wherein the agents interact with a peptide epitope tag (page 2, paragraph 0010, page 5, paragraph 0055), contacting said array with a solution of polypeptides (page 30, paragraphs 0313-0314); and detecting the presence and amount of the target protein or other proteins (page 26, paragraph 0270; page 2, paragraph 0015).

Ault-Riche et al. do not specifically teach a preparing a sample with denaturation or cleavage, nor does Ault-Riche et al. teach quantitating the amount of a target protein by averaging the results of each capture agent.

Regarding claims 1 and 19-21, Wagner et al. also teach a method of detecting proteins using arrays of protein-capture agents (abstract) which includes contacting the array with cleaved or denatured protein analytes (membrane bound proteins) from body fluids (column 35, lines 22-44) and quantitating the amount of a target protein by averaging the result (including if the total amount of the detected proteins is averaged by one spot in the array) (column 35, line 63-column 36, line 23; column 39, lines 12-50).

Regarding claim 2-5 and 38-41, Ault-Riche et al. teach wherein the capture agents specifically bind to a different PET of a target protein (page 17, paragraph 0181

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– page 18, paragraph 0184); wherein the different capture agents belong to the same category of capture agent such as antibodies or single chain antibodies (page 17, paragraph 0175; page 7, paragraph 0072); wherein the capture agents belong to different categories of capture agent (page 6, paragraph 0063 - page 7, 0068).

Regarding claim 6, Wagner et al. teach arrays with capture agents bind to the same PET and belong to a different category (column 12, line 14 - column 13, line 30).

Regarding claims 7-11, Wagner et al. teach using cellular extracts which would contain multiple forms of protein such as pro-form or mature form proteins, splicing forms, unmodified or post-translationally modified proteins (column 35, lines 22-44).

Regarding claims 12 and 13, Wagner et al. teach detecting protein fragments (processed forms) of cellular extracts and determining the ration of one form of protein to another form (column 45, lines 32-39; column 38, lines 43-65).

Regarding claim 22, Wagner et al. teach detection by ellipsometry or surface plasmon resonance (column 37, lines 6-26; column 36, lines 1-24)

Regarding claim 23, Wagner et al. teach wherein a secondary capture agent may be used for detection using fluorescent methods (column 36, lines 24-57).

Regarding claim 27, Wagner et al. teach wherein the PET is identified based on a sequenced genome (column 30, lines 42-54).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Ault-Riche et al. and Wagner et al. to gain the benefit of using different detection devices. Ault-Riche et al. and Wagner et al. teach similar methods of detecting and quantitating proteins in a sample with arrays. Ault-

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Riche et al. teaches any number of methods may be used to detect captured proteins of peptides (Ault-Riche, page 26, paragraph 0275), but does not teach specific methods of detection. Wagner et al. teaches using many different detection methods (Wagner, column 37, lines 6-26; column 36, lines 1-24). Thus one of ordinary skill in the art would be motivated to combine the references of Ault-Riche et al. and Wagner et al. to apply different detection devices to Ault-Riche et al.'s method.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

JL

